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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,915	04/19/2005	Motokazu Iwata	2005_0685A	3795

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EXAMINER	
HEINCER, LIAM J	

ART UNIT	PAPER NUMBER
1796	

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11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,915	IWATA ET AL.	
	Examiner	Art Unit	
	Liam J. Heincer	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.
Considering Claims 1 and 4: Nomura et al. teaches a composition comprising mannitol/a substance capable of providing aldehyde (¶0027) which further comprises a low molecular weight active substance (¶0021) and L-arginine (¶0025).
Considering Claim 5-7: Nomura et al. teaches the components as being present in a powdered form (¶0020).
Considering Claims 8-10: Instant claims 8-10 are product-by-process claims. Product-by-process claims are evaluated by the structure that the process implies, not necessarily the process itself. As Nomura et al. appears to provide a composition that is substantially the same as claimed in the instant claims, the claims are considered anticipated. See MPEP 2173.05.

Claims 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.
Considering Claim 11: Nomura et al. teaches a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Claims 16 and 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura et al. (WO 01/74397). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.
Considering Claim 16 and 17 : Nomura et al. teaches mixing (¶0020) mannitol, or starch/a substance capable of providing aldehyde (¶0027) with a low molecular weight active substance (¶0021) and L-arginine (¶0025).
Considering Claim 20: Nomura et al. teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) as applied to claim 11 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.
Considering Claims 12-15: Nomura et al. teaches the composition of claim 11 as shown above.

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming fine granules (4:2), which can be incorporated into a capsule or tablet (9:31-54) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation

to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) as applied to claim 16 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document. Considering Claims 18 and 19: Nomura et al. teaches the composition of claim 16 as shown above. Nomura et al. also teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming granules (4:2) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

Note: The rejection below is being presented to further prosecution should applicant provide evidence to show that section relied upon in Nomura et al. was not present in the WIPO publication.

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) in view of Battersby et al. (US Pat. 5,130,255). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 1 and 4: Nomura et al. teaches a composition comprising mannitol, or starch/a substance capable of providing aldehyde (¶0027) which further comprises an active substance (¶0021) and L-arginine (¶0025).

Nomura et al. does not teach the active substance as being a low molecular weight compound. However, Battersby et al. teaches a low molecular weight compound (4:25-29) in conjunction with a primary amine functional stabilizer (6:50-7:30). Nomura et al. and Battersby et al. are analogous art as they are concerned with the same field of endeavor, namely pharmaceutical compositions comprising amine functional stabilizers. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the compounds of Battersby et al. in the comprosition of Nomura et al., and the motivation to do so would have been, as Battersby et al. suggests, to treat different disorders (4:18-29).

Considering Claim 5-7: Nomura et al. teaches the components as being present in a powdered form (¶0020).

Considering Claims 8-10: Instant claims 8-10 are product-by-process claims. Product-by-process claims are evaluated by the structure that the process implies, not necessarily the process itself. As Nomura et al. appears to provide a composition that is substantially the same as claimed in the instant claims, the claims are considered anticipated. See MPEP 2173.05.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) in view of Battersby et al. (US Pat. 5,130,255). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claim 11: Nomura et al. teaches a solution/mass comprising mannitol and L-arginine and a solution/mass comprising an active substance (¶0048).

Nomura et al. does not teach the active substance as being a low molecular weight compound. However, Battersby et al. teaches a low molecular weight compound (4:25-29) in conjunction with a primary amine functional stabilizer (6:50-7:30). Nomura et al. and Battersby et al. are analogous art as they are concerned with the same field of endeavor, namely pharmaceutical compositions comprising amine functional stabilizers. It would have

been obvious to a person having ordinary skill in the art at the time of invention to have used the compounds of Battersby et al. in the comprosition of Nomura et al., and the motivation to do so would have been, as Battersby et al. suggests, to treat different disorders (4:18-29).

Claims 16, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) in view of Battersby et al. (US Pat. 5,130,255). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claim 16 and 17 : Nomura et al. teaches mixing (¶0020) mannitol, or starch/a substance capable of providing aldehyde (¶0027) with an active substance (¶0021) and L-arginine (¶0025).

Nomura et al. does not teach the active substance as being a low molecular weight compound. However, Battersby et al. teaches a low molecular weight compound (4:25-29) in conjunction with a primary amine functional stabilizer (6:50-7:30). Nomura et al. and Battersby et al. are analogous art as they are concerned with the same field of endeavor, namely pharmaceutical compositions comprising amine functional stabilizers. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the compounds of Battersby et al. in the comprosition of Nomura et al., and the motivation to do so would have been, as Battersby et al. suggests, to treat different disorders (4:18-29).

Considering Claim 20: Nomura et al. teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising a low molecular weight (¶0021) active substance (¶0048).

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) in view of Battersby et al. (US Pat. 5,130,255) as applied to claim 11 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 12-15: Nomura et al. and Battersby et al. collectively teach the composition of claim 11 as shown above.

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming fine granules (4:2), which can be incorporated into a capsule or tablet (9:31-54) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al. (WO 01/74397) in view of Battersby et al. (US Pat. 5,130,255) as applied to claim 16 above, and further in view of Kurihara et al. (US Pat. 5,726,180). Note: US 2005/0037084 is being used as an English language equivalent of WO 01/74397 and all citations will be directed towards this document.

Considering Claims 18 and 19: Nomura et al. and Battersby et al. collectively teach the composition of claim 16 as shown above. Nomura et al. also teaches preparing a solution/mass comprising mannitol and L-arginine and a solution/mass comprising anactive substance (¶0048).

Nomura et al. does not teach the masses as being in the form of granules. However, Kurihara et al. teaches forming granules (4:2) of the ingredients of a drug composition where the ingredients are separated (8:6-11). Nomura et al. and Kurihara et al. are combinable as they are concerned with a similar technical difficulty, namely forming stable drug compositions. It would have been obvious to a person having ordinary skill in the art at the time of invention to have formed fine granules of Kurihara et al. in the composition of Nomura et al., and the motivation to do so would have been, as Kurihara et al. suggests, it will improve the stability of the composition for a longer period of time (abstract).

Response to Arguments

Applicant's arguments filed August 13, 2008 have been fully considered but they are not persuasive, because:

A) Applicants argument that Nomura et al. only teaches high molecular weight compounds in the working examples is not persuasive. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied,* 493 U.S. 975 (1989). See MPEP 2123. The fact that Nomura et al. only uses high molecular weight in the examples does not negate the fact that lower molecular weight species are envisioned in the document (¶0021).

Additionally, the applicant has alleged that the information relied upon in the English language equivalent is not present in the WIPO Publication. As the specification of a national stage entry is required to a translation of the international application and amendments cannot be incorporated into the translation, the United States applicaiton is presumed to be substantially identical to the international application. See MPEP § 1893.01(d). As the applicant has provided no evidence to rebut this presumption, it is still considered valid. Additionally, should the applicant provide evidence to support their allegation, they are advised that the EPO publication, which was published prior to the effective filing date but after the foreign priority date, also contains the passage relied upon (¶0021). Therefore, a certified translation of the priority documents should also be included in the response to overcome the EP 1273306 document.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to

37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/ LJH
Supervisory Patent Examiner, Art Unit 1796 November 10, 2008